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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,081	09/04/2007	Gareth Wyn Roberts	620-409	7104

23117 7590 09/29/2010

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EXAMINER	
CLOW, LORI A	

ART UNIT	PAPER NUMBER
1631	

MAIL DATE	DELIVERY MODE
09/29/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/564,081	ROBERTS ET AL.	
	Examiner	Art Unit	
	LORI A. CLOW	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/11/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Status

Claims 1-19 are pending and under exam herein.

Priority

This Application is a US National Stage filing of GB 04/02979, claiming priority to US Provisional Application 60/486,239, filed 11 July 2003, of which papers have been received. Priority is acknowledged.

Information Disclosure Statement

The Information Disclosure Statement filed 11 January 2006 has been considered. A signed copy of PTO form 1449 is included with this Office Action.

Drawings

No Drawings have been submitted.

Compact Disc Submission

The CRF submitted 9 March 2008 has been entered.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or

other form of browser-executable code. See MPEP § 608.01. See page 18, line 16. Correction is requested.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-19 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Based upon consideration of all of the relevant factors with respect to the claim as a whole, claims 1-19 are held to claim an abstract idea, and are therefore rejected as ineligible subject matter under 35 U.S.C. 101. The rationale for this finding is explained below:

Making reference to the *Interim Guidance for Determining Subject Matter Eligibility for Process Claims in View of Bilski v. Kappos* (75 FR 43922 at 43927 (27 July 2010)), factors that weigh against the eligibility of a process claim include the following: 1) no express or inherent recitation of a machine or transformation and 2) claiming merely a statement of a general concept, such that it includes, for example, mathematical concepts such as algorithms, spatial relationships, geometry, data manipulation etc…

In the instant case, claims 1-19 are not patent eligible under the *Interim Guidance* because the claims merely recite mathematical concepts of manipulating data by providing a first, second and third dataset and determining risk factors and lifestyle recommendations and finally generating a personalized assessment of supplement requirements. The instant claim fail, however, to recite either a machine on which to perform such steps or an actual transformation of

the data to a different state or thing. The "computer implemented" method does not provide sufficient recitation of a machine, as it unclear as to what steps are performed by a computer and the machine is merely generically recited such that it covers any machine capable of performing the claimed method steps. As such, the claims are non-statutory.

Claim Rejections - 35 USC § 112-2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites, " determining at least one appropriate supplement recommendation (step v)". It is unclear what is meant by an "appropriate" recommendation. What constitutes "appropriate"? Does this mean that the recommendation is "appropriate" based upon the particular risk associated with that allele? For example, if the allele were associated with liver disease would the "appropriate" advice be to take milk thistle supplements ? Clarification is requested.

Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are as follows:

Claim 1 recites step (iii) inputting a third dataset identifying alleles at one or more of the genetic loci of said first dataset of said human subject. It appears that this step is missing an

element which makes it clear whether the input data from the individual human sample in step (iii) is different from the dataset of (i), which includes all of the known disease associated alleles.

Claim 1 recites step (iv) determining the risk factors associated with said alleles of said human subject using the first dataset. Again, it seems that an element is missing in (i) such that it is unclear whether the risk factors identified in (iv) are performed by comparing the individual's data with a set of generic, known data generated from a variety of samples.

Claim 1 recites step (v) determining at least one supplement recommendation based on each identified risk factor from step (iv) using said second dataset. Again, how does the data of this step relate to said dataset for step (ii)?

Claim 1 recites step (vi) generating a personalized assessment of supplement requirements based on said lifestyle recommendations. Does this mean that the supplement recommendation of the individual is generated based upon associated known risk factors of the second dataset? If so, it is still unclear that the second dataset is a dataset which is different from that of the patient (individual) sample.

Finally, it is unclear at step (iii) from where the third dataset is derived. It would seem that an essential element would be to actually determine the alleles from the individual sample such that they could be input and then evaluated. Clarification is requested.

Double Patenting-Obviousness

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible

harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-5, 12-15, and 17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 6-12 of copending Application No. 12/627,554. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '554 application are drawn to a computer assisted method of providing a personalized lifestyle advice plan that includes

generating a lifestyle advice plan based on lifestyle recommendations. The lifestyle advice plan includes recommended minimum and/or maximum amounts of food subtypes. The claims of the instant application are drawn to a computer assisted method of assessing personalized supplement requirements by implementing the same method steps to generate a personalized assessment of supplement requirements. The supplements therein can include a nutrient, which encompasses the "food subtypes" as instantly claimed. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have used the method steps of the instant claims for food supplement advice, as the lifestyle advice herein includes food subtypes.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

2. Claims 1-19 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-26 of U.S. Patent No. 7,054,758. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent claims are drawn to a computer assisted method of providing a personalized lifestyle advice plan that includes generating a lifestyle advice plan based on lifestyle recommendations. The lifestyle advice plan includes recommended minimum and/or maximum amounts of food subtypes. The claims of the instant application are drawn to a computer assisted method of assessing personalized supplement requirements by implementing the same method steps to generate a personalized assessment of supplement requirements. The supplements therein can include a nutrient, which encompasses the "food subtypes" as instantly claimed. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have

used the method steps of the instant claims for food supplement advice, as the lifestyle advice herein includes food subtypes.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-8, 10, and 12-19 are rejected under 35 U.S.C. 102(e) as being anticipated by WO 02/061659 (Gill-Garrison et al. Published 8 August 2002; PTO form 1449 reference).

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The instant claims are drawn to a computer assisted method of assessing personalized supplement requirements including providing a first dataset with information correlating the presence of individual alleles at a genetic loci with a lifestyle risk factor, wherein the genetic locus is known to be associated with increased or decreased disease susceptibility; providing a

second dataset comprising information matching each risk factor with at least one supplement, inputting a third dataset identifying alleles at one or more genetic loci of the first dataset; determining risk factors associated with said alleles using the first dataset; determining at least one appropriate supplement recommendation based on each identified risk factor; and generating a personalized assessment of supplement requirements.

In regard to claims 1, 7, 18 and 19 Gill-Garrison et al. teach the steps of claim 1 at page 8, lines 5-32. The lifestyle recommendations include recommendations for dietary factors (at page 9, line 2-this would inherently include supplements).

In regard to claim 2, Gill-Garrison et al. teach nutrients or therapeutic supplements at page 9, lines 15-17.

In regard to claim 3, Gill-Garrison et al. teach recommending minimum and/or maximum amounts of a supplement (page 9, line 18; wherein foodtypes include supplements).

In regard to claims 4 and 8, Gill-Garrison et al. teach producing a report for the personalized assessment (page 10, lines 7-17).

In regard to claim 5, Gill-Garrison et al. teach delivering the report to a client (page 10, lines 7-17).

In regard to claims 6 and 10, Gill-Garrison et al. teach dietary advice, which includes recipes (in the broadest most reasonable interpretation of the claim language) (increase consumption of food products known to increase Phase II metabolism in individuals that have polymorphisms associated with cancer risk-page 18, lines 7-18; eat broccoli, garlic, onion in individuals with low glutathione-S-transferase activity-page 24, lines 1-10).

In regard to claims 12-14 and 17, Gill-Garrison et al. teach the alleles as set forth in claims 12-14 (see pages 10-31).

In regard to claim 15, Gill-Garrison et al. teach DNA samples to assess individual alleles (page 31-32).

In regard to claim 16, Gill-Garrison et al. teach hybridization assays (page 34).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9 and 11 are rejected under 35 U.S.C. 103(a) as being obvious over WO 02/061659 (Gill-Garrison et al. Published 8 August 2002), as applied to claim 1 above in view of 2003/0069757 (Greenberg; Published 10 April 2003).

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The instant claims are drawn to a computer assisted method of assessing personalized supplement requirements including providing a first dataset with information correlating the presence of individual alleles at a genetic loci with a lifestyle risk factor, wherein the genetic locus is known to be associated with increased or decreased disease susceptibility; providing a

second dataset comprising information matching each risk factor with at least one supplement, inputting a third dataset identifying alleles at one or more genetic loci of the first dataset; determining risk factors associated with said alleles using the first dataset; determining at least one appropriate supplement recommendation based on each identified risk factor; and generating a personalized assessment of supplement requirements.

In regard to claims 1 Gill-Garrison et al. teach the steps of claim 1 at page 8, lines 5-32. The lifestyle recommendations include recommendations for dietary factors (at page 9, line 2- this would inherently include supplements).

Gill-Garrison et al do not specifically teach a kit with preparations of supplements and delivery of the kit as in claims 9 and 11. However, Greenberg teaches systems and methods for delivering a nutritional supplement regime which may be assembled in to a kit for delivery (abstract). It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have combined the methods of Gill-Garrison et al. with the capability of nutritional supplement delivery in kit form, as taught by Greenberg. One would have been motivated to do so, as the goal of Gill-Garrison et al is to deliver nutritional advice based on risk factors assessed. Including supplements in a kit would have been obvious, as Greenberg teaches doing so to support a healthy lifestyle (paragraph [0002]).

No claims are allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

September 28, 2010
/Lori A. Clow, Ph.D./
Primary Patent Examiner
Art Unit 1631